MIDTERM EVALUATION OF THE FAMILY HEALTH INTERNATIONAL (FHI) COOPERATIVE AGREEMENT (936-3041)

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by

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TABLE OF CONTENTS

APPENDICES

ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
AIDSCAP	AIDS Control and Prevention Project
AIDSTECH	AIDS Technical Support Project
AVSC	Association for Voluntary Surgical Contraception
CA	Cooperating Agency
CDC	Center for Disease Control and Prevention
CLM	Contraceptive Logistics Management Division of USAID's Office of Population
CONRAD	Contraceptive Research and Development Project
CQI	Condom Quality Index
CT	Clinical Trials Division
CTO	Cognizant Technical Officer
CTU	Contraceptive Technology Update
CUE	Contraceptive Use and Epidemiology Division
EIS	Executive Information System
FHI	Family Health International
FHRC	Family Health Research Center
FO	Field Operations Division
FPSD	Family Planning Service Delivery Division of USAID's Office of Population
FY	Fiscal Year
GLP	Good Laboratory Practice
HIV	Human Immunodeficiency Virus
IDE	Investigational Device Exemption
IND	Investigational New Drug
INOPAL	Operations Research in Family Planning and Maternal-Child Health for Latin America and the Caribbean Project
INTRAH	Program for International Training in Health Project
IPPF	International Planned Parenthood Federation
IPPF/WHR	International Planned Parenthood Federation/Western Hemisphere Region
IUD	Intrauterine Device
IWHC	International Women's Health Coalition
JHPIEGO	Johns Hopkins Program for International Education in Reproductive Health
JSI	John Snow Incorporated
LAM	Lactational Amenorrhea Method
LDC	Less Developed Country
MAQ	Maximizing Access and Quality of Care
MT	Materials Technology Division
NET	Norethindrone
NICHD	National Institute of Child Health and Development (NIH)
NIH	National Institutes of Health
OC	Oral Contraceptive
OR	Operations Research
PAHO	Pan American Health Organization
PATH	Program for Appropriate Technology in Health
PPD	Production and Process Development Unit
PPD	Population Program Development Unit
PPR	Population Program Research

PQ/C	Product Quality and Compliance Unit of MT
PRU	Policy and Research Utilization Division
RA/QA	Regulatory Affairs and Quality Assurance Division
R&D	Research and Development
RFP	Request for Proposal
SDR	Service Delivery Research Division
SOP	Standard Operating Procedure
SSS	Scientific Support Services Division
STD	Sexually Transmitted Disease
UNFPA	United Nations Population Fund
TAC	Technical Advisory Committee
USAID	United States Agency for International Development
USFDA	United States Food and Drug Administration
WHO	World Health Organization

PROJECT IDENTIFICATION DATA

1.	**Project Title:**	Family Health International (FHI)
2.	**Project Number:**	936-3041
3.	**Project Dates:**	
	Agreement Signed:	August 31, 1990
	End Date:	September 30, 1995
4.	**Project Funding:**	
	LOP (FY 1985–94):	$167,900,000
	Obligations to Date:	$101,367,265
5.	**Mode of Implementation:**	Cooperative Agreement
6.	**Responsible USAID officials:**	
	CTO:	Jeff Spieler, Acting Chief, Research Division
	Technical Adviser:	Judy M. Manning
7.	**Previous Evaluations:**	1984; 1989

ACKNOWLEDGMENTS

The team would like to express appreciation to the senior management and staff of FHI for the excellent assistance and cooperation provided for this evaluation.

EXECUTIVE SUMMARY AND MAJOR RECOMMENDATIONS

Introduction

Since 1971, Family Health International (FHI) has been USAID's principal vehicle for development, assessment, and transfer of new and improved contraceptive technology for use in developing countries. Under the current Cooperative Agreement, FHI's focus is on research and related activities required to develop and introduce new contraceptive technology and evaluate existing and improved methods of family planning. In general, FHI has carried out activities in a very effective manner and in accordance with the terms of the Cooperative Agreement. In looking to the next Agreement, FHI should (1) be more proactive in developing its own portfolio of contraceptive technology initiatives; (2) continue its trend toward embracing the paradigm of reproductive health; (3) retain its focus on research; and (4) take more initiative in seeking collaboration with other Cooperating Agencies (CAs). USAID should develop a monitoring system which gives coordinated attention to all areas of activity funded by the Agreement.

General Program Process

Mandate and Strategic Vision

FHI's mandate is set forth clearly in its Cooperative Agreement with USAID. In contraceptive research and development, FHI is to continue "its broad based program of research, development and evaluation and introduction of new and improved methods of fertility regulation." This involves a major effort, inter alia, in conducting studies and preparing documentation to obtain United States Food and Drug Administration (USFDA) certification to evaluate clinically and then market new contraceptive drugs and devices. In Population Program Research (PPR), the focus is on taking the contraceptive technologies developed through efforts of research and development and making them available to programs and users in developing countries. The evaluation team concludes that FHI has a strategic vision of its mission which conforms to its mandate but should be more proactive in developing its own portfolio of contraceptive technology initiatives.

Recommendation:

- FHI should be more proactive and develop its own portfolio of contraceptive technology initiatives.

Planning and Priority Setting

FHI, with the participation of USAID, has an effective planning process for activities funded under the Cooperative Agreement. In addition to the interaction between FHI and USAID, the Technical Advisory Committee (TAC) meeting provides a further opportunity in the planning process to address specific issues posed by FHI, primarily in the area of contraceptive development. The team believes, however, that the TAC should play a more substantial role in the process of planning and setting priorities.

Recommendation:

- Use of the TAC should be strengthened in three respects: materials prepared for TAC meetings should provide a clear view of proposed work plan priorities and activities; TAC meetings should be of adequate duration; and there should be increased representation of the social sciences.

Strengths and Weaknesses

FHI's strengths include an effective organization, well-qualified and motivated staff, and sustained budgetary support from and good working relationships with USAID. In addition, FHI has great strengths in the area of large-scale clinical trials and condom development and evaluation. These strengths, together with the strengths of the Population Program Department, have resulted in FHI's achieving virtually all of the objectives set forth in the Cooperative Agreement. FHI's weaknesses are few. There is a need for increased initiatives in contraceptive development, and senior management should make a greater effort to encourage innovation on the part of staff at all levels.

Recommendation:

- Senior management should ensure that staff members at all levels are actively encouraged to propose new initiatives.

Outputs

Certain outputs were designated in the Project Log Frame for the 10-year period of this and the previous Cooperative Agreement. FHI has met or exceeded outputs in every category.

General Research Agenda

FHI's Professional Standing and Management of its Research

Most CAs contacted by the team praised the excellence of FHI's research. The fact that other CAs regard FHI as a valuable research resource suggests that its work compares well with that of other CAs. The breadth of issues addressed by FHI staff in published articles, monographs, and books is impressive. Articles address significant issues, often researched in large, multi-country studies.

The team did not detect major problems in designing and implementing research projects. The evaluation team does understand that the idea of project/product champions in project teams has recently been reinstituted.

Recommendation:

- The project team leader, wherever possible, should be the one to decide when meetings are needed, what should be on the agenda, and who should attend. The administrative person, who currently calls the meetings and acts as chair, should still attend the meetings and be responsible for all other functions currently performed.

Clinical Trials

The work of the Clinical Trials Division is currently concentrated in four areas: barrier methods/spermicides, long-acting hormonal methods, sterilization, and "other" methods (intrauterine devices [IUDs] and mechanistic studies). Further studies with Lea's Shield and norethindrone (NET) preparations are in doubt for reasons beyond FHI's control, indicating the need for development of alternative strategies.

Recommendations:

- The Clinical Trials Division is encouraged to develop new initiatives for trials and to collaborate with other CAs wherever possible.

- There should always be funds available to permit the supervisor of the clinical trial monitors, project clinicians, or project leaders, as appropriate, to go the site of the field audits and supervise the work of the monitors.

Regulatory Affairs/Quality Assurance

This is a small, but key, support division. The division interacts on a regular basis with USFDA on clinical trials and is responsible for completion and submission of investigational device exemptions (IDEs), investigational new drugs (INDs), and 510Ks. It is anticipated that three 510Ks and three IDEs will be completed in the next year. The Regulatory Affairs and Quality Assurance Division (RA/QA) also plans to improve quality assurance and to increase training activities for the benefit of the research and development (R&D) group.

Recommendation:

- RA/QA should be encouraged to expand activities as proposed. Staff members should be added as needed to undertake these additional functions.

Interdivisional Working Groups

FHI has eight Interdivisional Working Groups. These vary in terms of when they were established and how active they are. One, New Contraceptive Technology Development, met for the first time in March 1994 and apparently has not met since. The most active Working

Groups in the Population Program area are Maximizing Access and Quality (MAQ) and Family Planning/Contraception/Sexually Transmitted Disease [STD]-HIV.

While the Interdivisional Working Group mechanism has been quite successful in bringing together relevant FHI divisions, there is evidence that not all relevant units are active participants in some Working Groups.

Recommendation:

- The Interdivisional Working Group mechanism should be strengthened so that the synergistic benefits of having all relevant FHI divisions involved in a given area can be achieved.

Materials Technology Division

The Materials Technology Division (MT) is divided into three units: Product Quality and Compliance (PQ/C), Product and Process Development (PPD), and a central staff unit. The expertise in PQ/C was developed to meet the need for condom evaluation for USAID's Contraceptive Logistics Management (CLM) Division. The evaluation team felt that PQ/C was providing valuable services to CLM, and if the increased workload engendered by testing other contraceptives required additional staff and space, these should be provided.

Through its PPD unit, MT supports work on the design, production, and testing of plastic condoms. Work continues on design of test equipment and ways to characterize plastic condoms that will equate to field acceptability. There is also formulation work on iodine for use in female sterilization. Stability of existing preparations has proved to be a problem, and to prepare a suitable formulation that is still active may be technically difficult.

There is good interaction between MT units and other divisions. MT units provide a useful service for Clinical Trials, especially with regard to the work on plastic condoms.

Recommendations:

- Product Quality and Compliance activities should continue and be expanded to cover other contraceptives distributed by USAID.

- USAID should provide approximately $750,000 per year for the publication of Network. It should be FHI's responsibility to secure additional required resources to ensure that Network is continued at its present level of quality.

- Additional space for the formulation work should be provided expeditiously. The most important need is to have all activities of MT at a single location.

- The original study with iodine should be repeated with a freshly prepared sample of the same formulation, irrespective of its stability on storage. If this produces the same results reported previously, the study will provide a benchmark against which to test all further iodine formulations. If the study in rabbits fails to confirm these results, the project should be abandoned.

Policy and Research Utilization and Dissemination of Research

The Network publication is of recognized quality. Typically, an edition of Network will focus on a theme such as quality of care, adolescents, or family planning/STDs. The translation of the publication into Spanish and French makes Network now available to many Third World audiences who have little or no knowledge of English. The rapid expansion of Network has, however, entailed a substantial expansion of the budget for the publication to a level which is unacceptable to USAID. FHI has a newer initiative to develop contraceptive technology update modules designed to expand FHI's reach beyond its workshops. There is no information yet as to the usefulness of the modules.

Contraceptive Utilization and Epidemiology

The Contraceptive Utilization and Epidemiology Division's (CUE's) objective is to "increase the availability, acceptance and correct use of a wide variety of family planning methods for the limitation and spacing of births to, and general reproductive health of, women in developing countries." CUE's studies include the Materials and Technology Division with latex and plastic condoms, oral contraceptive compliance in clinical and nonclinical settings and oral contraceptive package inserts, and effectiveness of barrier methods on STD/HIV prevention.

Recommendations:

- The excellent initiatives in the STD/AIDS field should be expanded and should be sensitive to future AIDSCAP policy. AIDSCAP already supports behavioral research; a mechanism needs to be developed to allow AIDSCAP to support epidemiological research on new condoms and spermicides/virucides.

- USAID should support the proposed study of oral contraceptives and Depo-Provera and HIV transmission. Once the difficult design issues are worked through, the study should be conducted in a developing country where the protocol can be monitored by qualified persons.

Service Delivery Research and Field Operations

The Service Delivery Research Division (SDR) is engaged in an important series of studies examining quality of care, resource allocation and sustainability, programmatic outcomes of the introduction of new contraceptive methods and new delivery systems, and, under development, issues relating to integration of STD/HIV prevention into family planning programs. The work of the division is closely integrated with the Maximizing Access and Quality initiative.

Field Operations, essentially a support or facilitating division, helps identify country needs, provides USAID Missions with information about FHI, and serves as liaison to FHI's country and regional offices.

Recommendation:

- SDR should give priority to studying the complex task of estimating the costs of integrating other reproductive health services (STDs, Pap smears, etc.) with family planning.

Personnel and Management Issues

FHI has a rational organization and management structure. Strong leadership for the whole of FHI is provided by the president. The vice presidents for the Research and Development and Population Program Departments have appointed excellent people to be division directors. FHI has also been very successful in recruiting and retaining qualified staff. The evaluation team found that most staff members are highly motivated and take pride in working at FHI.

Recommendations:

- All personnel needing to send and receive e-mail via Internet should be able to do so.

- The switch from dumb terminals accessing the Vax to personal computer networks should be accelerated. Greater server capacity is badly needed.

Budgeting and Funding

A review of expenditures and budgets over the life of the Agreement shows a moderate decrease in the portion for R&D and an increase for PPR. Within R&D, the MT and RA Divisions had significant increases. In the PPR area, the greatest proportional increases were in PRU and SDR. From a regional perspective, only one region, Asia and the Near East, experienced a decline in its budget.

Staff members of the Research Division of USAID's Population Office have stated that FHI's most important area of work under the Cooperative Agreement is contraceptive research and development, especially Phase II and III clinical trials. USAID would like to see slightly more than half of the total budget of the next Agreement devoted to contraceptive research and development.

Relationships With Other Organizations

In preparation for this evaluation, each division of FHI identified institutions with which it has been collaborating. Collaborating institutions include CAs, donor foundations, U.S. government agencies, international organizations, NGOs, universities, and developing country institutions. The evaluation team had discussions, mostly by telephone, with representatives of a number

of CAs. Persons interviewed felt that FHI provided a very useful resource in the area of research, especially clinical research and large clinical trials, and sought closer collaboration. In a few instances, there were some problems in achieving good working relationships. In most cases, these are reportedly being overcome. All USAID Missions responding to the request for an evaluation of FHI stated that FHI collaborated very effectively with other CAs in-country. The team did not find evidence of duplication of work among CAs.

Recommendation:

- FHI should take more initiative in seeking collaboration with CAs which have complementary roles and skills, especially the Population Council, CONRAD, and AVSC. USAID should encourage other CAs to collaborate with FHI.

FHI Relationships With USAID

Because the Cooperative Agreement specifies that USAID will be "substantially involved" during the performance of the Agreement, the issue of the relationship between FHI and USAID takes on special importance. Fortunately, the team found that, overall, relationships are excellent and are so perceived by key staff of both organizations. As noted above, USAID Missions were also very positive about FHI's performance.

Future Directions of a Follow-on Project

Recommendations:

- Priority for clinical studies should be placed on products that will be distributed by USAID. Where appropriate, clinical trials should be completed to USFDA standards.

- There should be a greater willingness to drop unpromising lines of investigation at an earlier stage.

- In developing plans for the next Cooperative Agreement, FHI should take account of USAID's view that contraceptive R&D, especially Phase II and III clinical trials, is FHI's most important area of work. The budgetary allocation should reflect this fact.

- FHI should continue its trend toward embracing the paradigm of reproductive health.

- FHI should retain its focus on research and be active in education, training, and information dissemination linked to that research. FHI should not attempt to become a "general purpose" CA but rather should continue to collaborate with other CAs that have complementary capabilities.

- USAID should develop a monitoring system for the next Agreement which gives coordinated attention to all areas of activity funded by the Agreement.

LIST OF RECOMMENDATIONS

1. FHI should be more proactive and develop its own portfolio of contraceptive technology initiatives. For example, barrier methods are a high priority, and, rather than wait for The Contraceptive Research and Development Program (CONRAD) to provide some spermicide/antimicrobial/antiviral compounds for test, FHI should establish a project team comprised of relevant FHI and CONRAD personnel to determine what may be most useful, what can be done to expedite the path to clinical testing, and how this is to be accomplished. Involvement of USFDA personnel may also be appropriate at some stage. Other initiatives could involve new formulations to permit large-scale testing of the progestin/androgen method of male contraception and interaction with The Population Council to become involved in studies of nesterone implants or rings. (Page 4)

2. Use of the TAC should be strengthened in three respects: materials prepared for TAC meetings should be in a form which gives TAC members a clear overview of FHI's proposed work plan priorities and activities; TAC meetings should be of adequate duration to permit review and discussion of FHI's proposed work plans; and there should be increased representation of relevant social sciences. (Page 5)

3. Senior management should ensure that staff members at all levels are actively encouraged to propose new initiatives. (Page 5)

4. The project team leader, wherever possible, should be the one to decide when meetings are needed, what should be on the agenda, and who should attend. As champion, it is in his/her interest to move the agenda forward as rapidly as possible. This person should also chair the meetings. (Page 8)

5. The staff member who currently calls the meetings and acts as chair should still attend the meetings and be responsible for minute-taking, recording action items, making and revising time lines, consulting with senior management about inputs, money, staff, and equipment needed to achieve the desired results. This person should also follow up on action items and report back to the team leader regarding problems and successes so that further meetings can be planned or alternative strategies pursued. (Page 8)

6. Clinical trials are encouraged to develop new initiatives for trials and to collaborate with other CAs wherever possible. (Page 9)

7. There should always be funds available to permit the supervisor of the clinical trial monitors, project clinicians, or project leaders as appropriate, to go to the site of the field audits and supervise the work of the monitors. (Page 9)

8. RA/QA should be encouraged to expand activities as proposed. Staff should be added as needed to undertake these additional functions. (Page 9)

9. Interdivisional Working Groups should be continued. A greater range of expertise should be included in the New Contraceptive Technology Development Group, perhaps with the addition of knowledgeable outsiders. Recommendations for action should be

reviewed by senior management and appropriate items presented to the TAC for discussion. (Page 11)

10. The Interdivisional Working Group mechanism should be strengthened so that the synergistic benefits of having all relevant FHI divisions involved in a given area can be achieved. (Page 11)

11. FHI should increase its efforts to measure both the short- and longer-term results of training and dissemination efforts under the MAQ initiative. (Page 11)

12. FHI, working in close collaboration with another appropriate CA, should take the initiative in planning for a comprehensive evaluation of the range of MAQ interventions in a family planning program which is lagging. Since it is claimed that successful application of the MAQ concept is equivalent to adding a new contraceptive method to a program, the evaluation should include an analysis of overall acceptor statistics and continuation rates in field settings. (Page 11)

13. Although the FHRCs are now independent, FHI, budget permitting, should remain sensitive to the research training needs of these institutions. As feasible, selected FHRC staff members might benefit from research fellowships at FHI, preferably to analyze their own data under the supervision of an FHI staff member. (Page 11)

14. Product Quality and Compliance activities should continue and be expanded to cover other contraceptives distributed by USAID. (Page 12)

15. FHI should recruit additional staff as needed to meet the requirements of CLM and reduce the workload on key team leaders. (Page 12)

16. FHI is encouraged to provide similar testing for other organizations provided that (1) it is done for profit or is at least fully reimbursed and (2) it does not adversely affect FHI's current workload. (Page 13)

17. Purchase of additional needed equipment for condom testing and evaluation should be expedited. (Page 14)

18. Additional space for the formulation work should be provided expeditiously. The most important need is to have all activities of MT at a single location. (Page 14)

19. Consultation with others who have had experience in formulation of iodine preparations should be done to ensure that unnecessary time and resources are not expended on a project that may prove to be technically difficult. Close interaction with the RA/QA Division is essential to ensure that relevant formulations are produced and funds are not expended on a project which, until animal efficacy is demonstrated, is questionable. (Page 14)

20. The original study with iodine should be repeated with a freshly prepared sample of the same formulation, irrespective of its stability on storage. If this produces the same results reported previously, the study will provide a benchmark against which to test all further iodine formulations. If the study in rabbits fails to confirm these results, the project should be abandoned. (Page 14)

21. Greater integration of the activities of RA/QA and MT is encouraged. (Page 14)

22. FHI should continue its excellent work of producing Network in English, Spanish, and French. It should also continue its practice of not limiting information in Network to research produced by FHI. (Page 15)

23. USAID should provide approximately $750,000 (or roughly 6 percent of the annual Cooperative Agreement budget) per year for the publication of Network. It should be FHI's responsibility to secure additional required resources to ensure that Network is continued at its present level of quality. (Page 15)

24. FHI should obtain additional information about the use and usefulness of Network which is distributed by bulk copy; it should also hold focus group interviews with readers (and non-readers) during field visits by FHI staff. (Page 15)

25. There should be prompt evaluations of the use, usefulness, and impact of the modules. If there is evidence that the modules are useful and they do not duplicate other available materials, the review and production process should be shortened. (Page 16)

26. Work on development of modules not already begun should await the results of the recommended evaluation. (Page 16)

27. The survey form included in the update package should be printed on airmail paper with an addressed airmail envelope attached. (Page 16)

28. FHI should consider producing a monograph describing and analyzing more comprehensively current programmatic experiments that are introducing selected reproductive health services into family planning programs in the developing world. (Page 17)

29. After completing many studies of the latex condom, the understanding of the determinants of condom breakage remain elusive. New protocols should be designed in order to disentangle the roles of condom age, product chemistry, user behaviors, and other factors in condom failure. (Page 18)

30. FHI should ensure that compliance studies are well integrated into the MAQ initiative. (Page 18)

31. FHI should explore existing data sets that could be useful in exploring the link between prostate cancer and vasectomy. (Page 18)

32. The excellent initiatives in the STD/AIDS field should be expanded and should be sensitive to future AIDSCAP policy. AIDSCAP already supports behavioral research; a mechanism needs to be developed to allow AIDSCAP to support epidemiological research on new condoms and spermicides/virucides. (Page 18)

33. USAID should support the proposed study of OCs and Depo-Provera and HIV transmission. Once the difficult design issues are worked through, the study should be conducted in a developing country where the protocol can be monitored by qualified persons. (Page 19)

34. The LAM clinical trials appear to be sufficient and can now cease. FHI should consider collaboration with FHRCs and experienced in-country investigators on local acceptability studies of Lea's Shield, Femcap, and the female condom. Research on specific issues, such as the acceptability and feasibility of reuse of the female condom, which are considered critical to the overall assessment of this method, should be continued by FHI. (Page 19)

35. SDR should explore how its conceptual work in the area of cost studies can be linked with systems of financial accounting that several Latin American family planning associations have developed as part of an effort to achieve greater financial sustainability. (Page 20)

36. SDR should give priority to studying the complex task of estimating the costs of integrating other reproductive health services (STDs, Pap smears, etc.) with family planning. (Page 20)

37. Without unnecessary replication of studies, the issues surrounding introduction/re-introduction of Depo-Provera and NORPLANT® should be addressed in important countries with a view to developing a manual based on lessons learned in the field. (Page 20)

38. Planning should begin for the introduction of the plastic condom into family planning programs and through other outlets. (Page 20)

39. The team supports the idea of modest expansion of FHI representation in countries that present substantial learning opportunities for service delivery or other research. (Page 20)

40. The team favors a more proactive approach by FHI to make USAID Missions aware of FHI's research capability and potential for strengthening programs. FO should develop such a strategy with other FHI divisions and plan appropriate visits by scientific staff to Missions in countries presenting special opportunities. (Page 20)

41. In order to better understand the process of "graduating" FHRC institutions and to provide guidance for the process for other institutions in the future, FHI should assess the research and financial status of several of the "graduated" FHRCs. SDR should be involved in this research. (Page 21)

42. More advanced training courses for selected computer software programs should be provided. Needs could be determined by a survey of personnel. (Page 24)

43. Training in management skills and techniques should be provided for supervisors, particularly at lower levels. (Page 24)

44. All personnel needing to send and receive e-mail via Internet should be able to do so. (Page 24)

45. The switch from dumb terminals accessing the Vax to personal computer networks should be accelerated. Greater server capacity is badly needed. (Page 24)

46. Without in any way impeding the current excellent system for internal communication, FHI might review the schedule and purposes of various meetings to determine whether some consolidation or streamlining is in order. (Page 24)

47. USAID should consider requiring annual, rather than semiannual, reports from FHI. Further, in the interests of reducing the reporting workload, FHI should explore how annual reporting could be combined with preparation of annual work plans. (Page 25)

48. Although, in times of budgetary constraints, reduction of travel budgets is an immediate way to solve the cash shortage, FHI is urged to restore these cuts as soon as possible. (Page 29)

49. FHI should take more initiative in seeking collaboration with CAs which have complementary roles and skills, especially The Population Council, CONRAD, and AVSC. USAID should encourage other CAs to collaborate with FHI. (Page 32)

50. Priority for clinical studies should be placed on products that will be distributed by USAID. Where appropriate, clinical trials should be performed to USFDA standards. (Page 37)

51. There should be a greater willingness to drop unpromising lines of investigation at an earlier stage. (Page 37)

52. The focus of FHI's R&D effort should be expanded, especially in collaborative efforts with other Cas. (Page 37)

53. The Quality Assurance/Production Surveillance component should be kept within the next Cooperative Agreement. (Page 37)

54. In developing plans for the next Cooperative Agreement, FHI should take account of USAID's view that contraceptive R&D, especially Phase II and III clinical trials, is FHI's most important area of work, and the proposed budgetary allocation should reflect this fact. (Page 37)

55. FHI should continue its trend toward embracing the paradigm of reproductive health. (Page 38)

56. FHI should retain its focus on research and be active in education, training, and dissemination of information which are linked to that research. FHI should not attempt, in the current or proposed next Cooperative Agreement, to become a "general purpose" CA but rather should continue to collaborate with other CAs which have complementary knowledge and capabilities. (Page 39)

57. The Women's Studies Project should be involved not only in the MAQ Working Group but in other relevant Working Groups, including, e.g., the Group concerned with postpartum contraception. The Women's Studies Project should also participate in planning any research looking at the effects and costs of integration of elements of reproductive health services into family planning. (Page 39)

58. AIDSCAP should be represented on FHI's Family Planning/Contraception/STD-HIV Working Group and Adolescent Reproductive Health Working Group. (Page 39)

59. FHI staff supported under the Cooperative Agreement, AIDSCAP staff, and AIDSCAP subcontractors should hold several informal (and small) meetings in the next fiscal year to define the critical research areas that are likely to influence AIDS control policy in the next years. Funds should be available under the next Agreement for FHI to pursue the most promising studies. (Page 39)

60. USAID should develop a monitoring system for the next Cooperative Agreement which gives coordinated attention to all areas of activity funded by the Agreement. (Page 39)

1. INTRODUCTION

1.1 Purpose of the Evaluation

Since 1971, Family Health International (FHI) has been USAID's principal vehicle for development, assessment, and transfer of new and improved contraceptive technology for use in developing countries. Under the current Cooperative Agreement, FHI's focus is on research and related activities required to develop and introduce new contraceptive technology and evaluate existing and improved methods of family planning. These activities include clinical trials of contraceptive methods to evaluate their efficacy and safety under clinical conditions and actual use in developing countries; evaluation of risks, benefits, and acceptability of new and existing contraceptive methods; strengthening research skills and management of developing country investigators, institutions, and programs; and disseminating technical information related to contraceptive technology to researchers, family planning programs, policy-makers, and administrators. The purpose of this evaluation is to determine how effectively FHI has carried out these activities. The major focus of the evaluation is to (1) assess the relevancy, management, and performance of the project; and (2) recommend any changes in such for the follow-on project. The Scope of Work for the evaluation is set forth in Appendix A.

1.2 Evaluation Materials

In preparation for the current evaluation, FHI prepared a very substantial amount of material on the organization and its research and other activities. The materials are in general of excellent quality, and they facilitated the task of evaluation.

1.3 FHI Response to Previous Evaluation

The previous evaluation team made more than 40 recommendations relating to FHI's organization, staffing, and programs. In preparation for the current evaluation, FHI prepared information indicating action taken with respect to each recommendation. The team has reviewed FHI's responses and concludes that appropriate action was taken in virtually every instance. In those cases where FHI did not take the recommended action, the reason was usually that the recommendation was not in accordance with USAID priorities of the time.

2. GENERAL PROGRAM PROCESS

2.1 Mandate and Strategic Vision

FHI's mandate under the Cooperative Agreement is set forth clearly in that document. Further, both short- and long-term goals are described in the Agreement and in annual work plans which require approval by USAID. FHI has noted in materials prepared for this evaluation that "over the past two decades, FHI, with support of USAID and other donors, has evolved....into a multidimensional research and technical assistance organization focusing more broadly on reproductive health issues." Based on a review of FHI documents and discussions with a number of FHI staff, the evaluation team concludes that, overall, FHI has a broad strategic vision. Now that FHI is a mature organization, it should strengthen and sharpen its own strategic vision, particularly in the area of contraceptive technology development and clinical trials.

2.1.1 Contraceptive Research and Development

The program description in the Cooperative Agreement states that "FHI intends to continue its broad-based program of research, development, evaluation and introduction of new and improved methods of fertility regulation." This involved major effort, *inter alia*, in conducting studies and preparing documentation to obtain United States Food and Drug Administration (USFDA) certification to evaluate clinically, and then market, new contraceptive drugs and devices.

Short-term goals were to focus on several leads already under development, specifically long-acting steroid delivery systems, oral contraceptives, female sterilization, male sterilization, intrauterine devices, barrier contraceptives and spermicides, and natural family planning and breast feeding, and to support on a case-by-case basis new investigator-initiated proposals. Work was also to be done on condom evaluation to determine the relationship between laboratory quality assurance standards and field performance. Obviously, as needs changed, the priority given to these different areas has shifted over the life of the project.

Discussions with both FHI senior management and staff from other Cooperating Agencies (CAs) revealed that FHI considers its primary role to respond to the needs of USAID. In some cases, senior management indicated that a rapid response to a new USAID initiative could impact the conduct of ongoing studies or trials. It was felt this was not always appreciated by USAID. It was the perception among other CAs that FHI was on occasion too compliant and did not have a particularly strong strategic vision. The evaluation team also sensed that the Contraceptive Research and Development component of FHI tended to be reactive rather than proactive. Although this may suit USAID/Washington, the team felt that this was not always the most healthy relationship.

1. Recommendation: **FHI should be more proactive and develop its own portfolio of contraceptive technology initiatives. For example, barrier methods are a high priority, and, rather than wait for The Contraceptive Research and Development Program (CONRAD) to provide some spermicide/antimicrobial/antiviral compounds for test, FHI should establish a project team comprised of relevant FHI and CONRAD personnel to determine what may be most useful, what can be done to expedite the path to clinical testing, and how this is to be accomplished. Involvement of USFDA personnel may also be appropriate at some stage. Other initiatives could involve new formulations to permit large-scale testing of the progestin/androgen method of male contraception and interaction with The Population Council to become involved in studies of nesterone implants or rings.**

2.1.2 Population Program Department

A review of materials prepared for the evaluation team on objectives, activities, and accomplishments of its several divisions, together with discussions with staff members of each division leads the team to conclude that this component of FHI has a clear strategic vision with both short- and long-term goals. Of particular note are the current efforts to broaden work beyond family planning by exploring the relationships of sexually transmitted diseases (STDs) and HIV to family planning and to search for ways to link facets of reproductive health to family planning services. Through studies evaluating the introduction, acceptability, costs, effectiveness, and safety of contraceptive methods, FHI has strengthened the capacity of developing country researchers and programs to provide and evaluate contraceptives, a major goal under the Cooperative Agreement.

2.2 Planning and Priority Setting

With respect to the planning process and setting priorities, this takes place annually in a series of meetings in which USAID participates and where the next year's work plan is developed. FHI senior staff stated that, while the Scientific Committee is the focus for strategic planning, the planning is both top-down and bottom-up. Although the team was apprised of certain examples where this bottom-up planning had occurred (e.g., clinical trials of cervical mucous changes in relation to time after NORPLANT® insertion and the initiatives in epidemiology), it was the impression of the team that these may be exceptions rather than the rule and that most of the priority setting came from the Scientific Committee in consultation with USAID.

In addition to the interaction between FHI and USAID, the Technical Advisory Committee (TAC) meeting has provided a further opportunity in the planning process to address specific issues posed by FHI, primarily in the area of contraceptive development. At the same time, the evaluation team believes that the TAC should play a more substantial and effective role in the process of planning and setting priorities, both in contraceptive technology development and population programs. To achieve this, FHI senior management should ensure that (1) plans and materials are prepared for TAC meetings in a form which gives TAC members the

opportunity to provide advice regarding work plan priorities; (2) the timing and duration of TAC meetings is appropriate to this objective; and (3) there is increased representation of the social sciences.

2. Recommendation: **Use of the TAC should be strengthened in three respects: materials prepared for TAC meetings should be in a form which gives TAC members a clear overview of FHI's proposed work plan priorities and activities; TAC meetings should be of adequate duration to permit review and discussion of FHI's proposed work plans; and there should be increased representation of relevant social sciences.**

The team does not believe that FHI is currently trying to do too much, although it is likely that choices will have to be made in coming years, particularly in the Population Programs Department, if budgets do not expand to keep pace with expanding program opportunities. This is discussed further in Chapter 5.

There is a certain tension between the requirements of USAID/Washington and USAID Missions, but FHI has been able to manage this effectively. FHI virtually never turns down a Mission request but, through discussions, has been able to modify requests so that they also meet FHI objectives. FHI has a need to accomplish research projects in developing countries, and this means there has to be accommodation with the Missions' objective to increase contraceptive prevalence.

2.3 Strengths and Weaknesses

FHI's overall strengths include an effective organizational structure, a well-qualified, highly motivated and productive staff, good intra-organizational working relationships, sustained budgetary support, sound management, and good working relationships with USAID. In addition, FHI has great strengths in the area of large-scale clinical trials and condom development and evaluation, and these strengths are not duplicated by any other CA. These strengths, together with the strengths of the Population Program Department, have resulted in FHI's being able, on a continuing basis, to achieve virtually all the objectives set forth in the Cooperative Agreement.

The evaluation team has been able to detect few overall weaknesses in FHI. Three areas which do deserve attention are (1) as mentioned above, increased initiatives on the contraceptive research and development side; (2) a greater effort by senior management to encourage innovation on the part of staff members at all levels; and (3) increased effort by FHI to develop collaborative relationships with CAs which have complementary skills and areas of responsibility.

3. Recommendation: **Senior management should ensure that staff members at all levels are actively encouraged to propose new initiatives.**

2.4 Outputs

Certain outputs were specified in the Project Log Frame for the 10-year period of this and the previous Cooperative Agreement. These outputs were 300 studies that will contribute to improved knowledge, program introduction, and method use; three major [contraceptive] methods introduced; 350 publications; and 12 developing country Family Health Research Centers developed or maintained.

Outputs have been met or exceeded in every category. In introduction of new methods alone, 12 major methods have been introduced (see Appendix B). Completed studies number 462 with an additional 100 under way (see Appendix C). There have been 352 publications. Further, as discussed in Section 3.9.5, FHI also organized a series of workshops, training courses, and meetings which are not included in the output count (see Appendix D). Regarding support to Family Health Research Centers, see Appendix E.

3. GENERAL RESEARCH AGENDA

3.1 Professional Standing of FHI and Scientific Merit of Its Research

Discussions were held with representatives of seven CAs that had collaborated with FHI in the area of contraceptive technology research and clinical trials. Most CAs praised the excellence of FHI's research. Comments included the following: the human use trials of condoms were tremendously important and of excellent quality; FHI is a very reliable research organization, takes suggestions well, and acts upon them efficiently; working with FHI is a very positive experience. Only one organization felt that some of FHI's past studies could have used more scientific rigor. In light of personnel changes which have taken place at FHI, and given the present need for most new studies to meet FDA standards, this is unlikely to be a problem in the future.

FHI's work, by and large, does not duplicate that of other CAs and therefore comparisons are difficult. The fact that other CAs regard FHI as a valuable research resource suggests that its work compares well with that of other CAs.

The breadth of the issues addressed by FHI's staff in published articles, monographs, and books is impressive. The original articles address significant issues, often researched in large, multicentered studies which can be difficult to conduct in developing country settings. The review articles demonstrate a firm grasp of the subjects they address. The team did not perform an analysis to determine how often FHI's publications are cited, but impressionistic evidence suggests that they are frequently cited in the growing body of contraceptive/family planning/HIV-AIDS literature.

3.2 Design and Management of Research Projects

The team did not detect any major problems in designing and implementing research projects. Some minor problems had surfaced in a few projects, mostly involving collaboration with other organizations. To facilitate such collaboration, it is necessary to document roles and expectations and assign a single person to be in charge of the project. It is also important to have as few personnel changes as possible during the life of the study. It is the perception of the evaluation team that the studies undertaken clearly reflect the objectives of the Cooperative Agreement. In fact, this is assured inasmuch as USAID staff is involved in setting priorities for yearly work plans.

Research management for contraceptive technology can be accomplished in many ways. One of the most effective is the use of project teams, with a designated champion for each project. The evaluation team understands that the idea of project/product champions in the project teams has only recently been reinstituted, although some teams have been in operation for several years. The use of project teams is commended, but project team leaders should be given increased authority and responsibility.

4. Recommendation: **The project team leader, wherever possible, should be the one to decide when meetings are needed, what should be on the agenda, and who should attend. As champion, it is in his/her interest to move the agenda forward as rapidly as possible. This person should also chair the meetings.**

5. Recommendation: **The staff member who currently calls the meetings and acts as chair should still attend the meetings and be responsible for minute-taking, recording action items, making and revising time lines, consulting with senior management about inputs, money, staff, and equipment needed to achieve the desired results. This person should also follow up on action items and report back to the team leader regarding problems and successes so that further meetings can be planned or alternative strategies pursued.**

3.3 Clinical Trials

The goal of the Clinical Trials Division (CT) is to increase information about and the number of safe, effective, and acceptable contraceptive methods for use in developing countries. The division is currently divided into five units which may not be optimal for providing staff with opportunities for greater responsibility. The director is currently exploring the possibility of reorganizing the division to address this need.

The technical expertise of many staff members has been gained on the job and, with a few exceptions, this may have constrained their abilities to generate new ideas. Section 3.6, Interdivisional Working Groups, discusses ways in which additional ideas might be generated for contraceptive development.

The division has had three directors in the last three years. Stability of leadership would make it possible to develop a more focused strategic plan.

Work at present is concentrated in four areas: barrier methods/spermicides (plastic condoms, Lea's shield, vaginal contraceptive film, and Reality™ female condom), long-acting hormonal methods (NORPLANT®, norethindrone [NET] biodegradable pellets, and NET 90 injectable), sterilization (no-scalpel vasectomy, Filshie clip, quinacrine, and iodine) and "other" methods (intrauterine devices [IUDs], pills, and mechanistic studies). Further studies with Lea's shield and the NET preparations are in doubt for reasons beyond FHI's control, indicating the need for development of alternative strategies. The new director is likely to be a very positive influence in this regard. Over the years this division has been very active and is one of the main strengths of FHI.

The evaluation team understands that funds are not routinely available to permit the supervisor of the clinical trial monitors to travel to the site of the field audits and supervise the work of the monitors. Lack of such supervision could affect FHI negatively if a problem in a trial should emerge after final analysis and dissemination of trial results.

6. Recommendation: **Clinical trials are encouraged to develop new initiatives for trials and to collaborate with other CAs wherever possible.**

7. Recommendation: **There should always be funds available to permit the supervisor of the clinical trial monitors, project clinicians, or project leaders as appropriate, to go to the site of the field audits and supervise the work of the monitors.**

3.4 Regulatory Affairs and Quality Assurance

Regulatory Affairs and Quality Assurance (RA/QA) is a small, but key, support division with six full-time staff. It was developed out of the data checking group in Biostatistics. The division interacts on a regular basis with USFDA on clinical trials and is responsible for completion and submission of investigational device exemptions (IDEs), investigational new drugs (INDs), and 510Ks. It is anticipated that three 510Ks and three IDEs will be completed in the next year, which represents a substantial workload. Quality assurance within FHI will be improved this year which will likely require additional staff. For the future, FHI intends to increase the division's training activities for the benefit of the research and development group. There is a desire to divide regulatory functions for drugs and devices into separate units because the regulations for these are different. This is not possible, however, with existing staff. In the future, a unit may also be needed to deal with biologics. Other initiatives in process include encouraging staff to respect standard operating procedures (SOPs) and to conduct more in-house audits of procedures.

8. Recommendation: **RA/QA should be encouraged to expand activities as proposed. Staff should be added as needed to undertake these additional functions.**

3.5 Biostatistics

The staff of the Biostatistics Division has been augmented over the past few years to work more effectively with clinicians in developing, implementing, and analyzing FHI's trials and, as needed, explaining the results to USFDA. Recently, the division began working with the Materials Technology Division (MT) to strengthen its product stability and quality control activities. Division staff also consults, as requested, with investigators in the Population Program Department of FHI. It is generally agreed that these interventions have improved the quality of FHI research.

3.6 Interdivisional Working Groups

FHI has eight Interdivisional Working Groups. These groups vary substantially in terms of when they were established, how active they are, how frequently they have made recommendations for action, and so forth. One Working Group, New Contraceptive Technology Development, met for the first time in March 1994 and apparently has not met since. The minutes of the meeting show the strong influence of the chair of this Working

Group, which is not surprising since he is the only member with much experience in the contraceptive R&D field. This Group should meet on a regular basis and should include additional persons with expertise in this area, perhaps even outsiders, such as TAC members.

The most active Working Groups in the Population Program Department area are Maximizing Access and Quality of Care (MAQ) and Family Planning/Contraception/STD-HIV. The MAQ Group has identified a variety of practical service delivery factors that inhibit family planning acceptance and continuation. To address these, it has implemented a number of projects and activities through the Policy Research and Utilization Division (PRU), the Service Delivery Research Division (SDR), and the Field Operations Division. Currently, the Group is refining its strategic plan, which includes initiatives in education and training, policy and practice revision, and research. The aim is to define more precisely the scope of MAQ for implementation by FHI.

Two important objectives of the MAQ activity are to reduce restrictive practices which limit access to family planning and improve knowledge and skills of reproductive health service providers. To this end, in Africa for example, FHI is working with The International Training in Health Project (INTRAH) in Cameroon and Ghana to introduce national family planning service guidelines. One vehicle to achieve this is a series of reproductive health update seminars for service providers and other key family planning community members. FHI's role in Ghana is to provide funding and technical assistance for the seminars; fund production and dissemination of the guidelines to public and private sector service providers; and conduct research on the impact of service guidelines on quality of care. In Cameroon, INTRAH is mainly responsible for development of guidelines and training to implement them, while FHI has taken the lead in disseminating information about contraceptive technology and measuring the impact of guidelines on service delivery practices. Under the MAQ umbrella, FHI is supporting similar activities in other developing regions. It is clear, therefore, that FHI is contributing through MAQ to the education and training of reproductive health workers in a number of settings. It has also begun to conduct research on the impact of its training and dissemination work.

The Family Planning/Contraception/STD-HIV Working Group, which has been meeting quarterly since September 1993, has focused on the appropriate integration of services, needed interventions, evaluation of the interaction between contraceptives and STD/HIV transmission, assessment of existing barrier methods, and development of new barrier methods. A variety of useful studies and reviews have been implemented by the Contraceptive Use and Epidemiology Division (CUE), the Materials Technology Division (MT), the Clinical Trial Division (CT), the Field Operations Division (FO), PRU, and SDR under the aegis of the Working Group.

While the Interdivisional Working Group mechanism has been quite successful in bringing together relevant FHI divisions to focus on some specific key issues, for example MAQ, the evaluation team found evidence that not all relevant FHI units were active participants in some Working Groups. Given that lines of authority and budgets for projects are organized vertically, which is appropriate, FHI should seek ways to strengthen the Interdivisional Working Group mechanism (including more frequent meetings of those Groups which have been relatively inactive) so that the synergistic benefits of having all relevant FHI units involved in a given area can be achieved.

9. Recommendation: **Interdivisional Working Groups should be continued. A greater range of expertise should be included in the New Contraceptive Technology Development Group, perhaps with the addition of knowledgeable outsiders. Recommendations for action should be reviewed by senior management and appropriate items presented to the TAC for discussion.**

10. Recommendation: **The Interdivisional Working Group mechanism should be strengthened so that the synergistic benefits of having all relevant FHI divisions involved in a given area can be achieved.**

11. Recommendation: **FHI should increase its efforts to measure both the short- and longer-term results of training and dissemination efforts under the MAQ initiative.**

12. Recommendation: **FHI, working in close collaboration with another appropriate CA, should take the initiative in planning for a comprehensive evaluation of the range of MAQ interventions in a family planning program which is lagging. Since it is claimed that successful application of the MAQ concept is equivalent to adding a new contraceptive method to a program, the evaluation should include an analysis of overall acceptor statistics and continuation rates in field settings.**

3.7 Strengthening Management and Research Skills in Developing Countries

FHI has actively attempted to improve the level of management and programmatic research capability in the developing world through seminars on research techniques, one-on-one training in the field and at headquarters, and information dissemination. While the principal focus has been on the staff of family health research centers (FHRCs), individual researchers working with FHI staff on research projects of mutual interest, including multicentered trials, have also benefited from formal and informal contacts with FHI staff. It is clear, then, that FHI has contributed significantly to the ability of developing country researchers to raise more hypotheses of relevance to their own situations, handle more complicated research designs, and participate more fully in the analysis of their own contraceptive/family planning data. Continued nurturing will be necessary, however, especially in data analysis using more sophisticated techniques and computer skills and in more elementary levels in countries that are at less sophisticated research levels.

13. Recommendation: **Although the FHRCs are now independent, FHI, budget permitting, should remain sensitive to the research training needs of these institutions. As feasible, selected FHRC staff members might benefit from research fellowships at FHI, preferably to analyze their own data under the supervision of an FHI staff member.**

3.8 Materials Technology Division

The Materials Technology Division is divided into three main groups. These are Product Quality and Compliance (PQ/C), Product and Process Development (PPD), and a central staff unit.

3.8.1 Product Quality and Compliance

The expertise in PQ/C was developed to meet the need for condom evaluation of USAID's Contraceptive Logistics Management (CLM) Division. Initially, FHI had no expertise in this area, and there was, therefore, a steep learning curve which has now borne fruit. The first condom testing, production surveillance, was done in 1990, which was broadened to cover all types of contraceptives distributed by USAID. This has caused the division to expand greatly. Provision of staff and equipment have not been constraints so far.

Since condom quality index (CQI) may or may not be a good predictor of condom quality, CLM has urged MT to evaluate statistically all its data to determine if better predictors of quality and improved specifications for the manufacturing process could be developed. CLM felt that this had not been done as expeditiously as possible, partly due to lack of statistical assistance. This has now been rectified and a report addressing these issues is to be presented at a joint meeting with CLM.

The addition of a staff person to undertake field audits has improved that process and freed existing staff for other activities. CLM feels that the level and quality of work is good but that FHI has not been proactive enough. The addition of a biostatistician, the establishment of a technical oversight committee, and the conduct of unannounced audits were all suggestions made by USAID, but should have come from FHI. Quality assurance is time sensitive since the manufacturer cannot ship the product until written disposition has been received from PQ/C. PQ/C is urged to continue to meet the two-week turnaround time currently achieved.

The evaluation team felt that PQ/C was providing valuable services to CLM, and if the increased workload engendered by testing other contraceptives requires additional staff and space, these should be provided. There is also the possibility of conducting similar tests for other organizations which might produce revenue. This is encouraged, provided it does not affect turnaround time.

14. Recommendation: Product Quality and Compliance activities should continue and be expanded to cover other contraceptives distributed by USAID.

15. Recommendation: FHI should recruit additional staff as needed to meet the requirements of CLM and reduce the workload on key team leaders.

16. Recommendation: **FHI is encouraged to provide similar testing for other organizations provided that (1) it is done for profit or is at least fully reimbursed and (2) it does not adversely affect FHI's current workload.**

3.8.2 Product and Process Development

MT also supports work on the design, production, and testing of plastic condoms. PPD is concerned with bringing these products to market as soon as possible. This work will support the 510K submissions. MT will finish the pilot manufacturing plant and provide the background for technology transfer when a manufacturer is identified. One staff member has been greatly involved in this work and in the filing of patents to protect FHI's proprietary rights. The staff member went to school at his own expense to learn patent law and is now a registered patent agent. FHI could make greater use of this staff member's talents.

Work is continuing on design of test equipment and ways to characterize the plastic condoms that will equate to field acceptability. There are also ongoing studies on characterization of latex condoms, packaging, effects of aging and temperature, and the reformulation of nonoxynol-9 to prevent its deleterious effect on plastic condoms at elevated temperatures. Some additional equipment may be needed, e.g., a differential scanning calorimeter and a dynamic tensile tester, for the condom research. To assist in this work, an additional technician with a physical chemistry background is needed.

There is also formulation work being done on iodine for use in female sterilization. Stability of existing preparations has proved to be a problem, and to prepare a suitable formulation that is still active may be technically difficult. Establishment of in vitro tests that correlate with in vivo effects on the oviduct, which was suggested by RA/QA staff, have much merit. However, the present facilities are not suitable for tissue culture studies. Appropriate hoods, incubators, and clean space are not available and therefore such tests may have to be farmed out. Since the efficacy of iodine to sclerose the oviducts in animals has not been confirmed, the original study by an outside scientist with iodine should be repeated in a small number of rabbits (4–6) with a freshly prepared sample of the same formulation of iodine, irrespective of its stability on storage. If this produces the same results reported by the scientist, the study will provide a benchmark against which to test all further iodine formulations. It should be anticipated that reformulation of iodine to produce stability may actually reduce its effectiveness as a sclerosing agent. If the study in rabbits fails to confirm the original results, the project should be abandoned.

A technician with a background in chemistry is being hired for this formulation work. Even if the iodine work is suspended, other projects requiring formulation expertise are under consideration. The present location of the formulation work is at the pilot plant, and this is not satisfactory. Extra space contiguous to the existing PQ/C laboratories is urgently needed for this formulation work. The staff time lost traveling between locations is wasteful and counterproductive. Even if the pilot plant cannot be moved immediately, the long-term plan should be to centralize all activities of MT at one site. The initial expense involved is such consolidation will be quickly saved in greater efficiency of the division. Any new location should be nearer FHI headquarters, unless FHI intends to move its headquarters in the near future.

17. Recommendation: **Purchase of additional needed equipment for condom testing and evaluation should be expedited.**

18. Recommendation: **Additional space for the formulation work should be provided expeditiously. The most important need is to have all activities of MT at a single location.**

19. Recommendation: **Consultation with others who have had experience in formulation of iodine preparations should be done to ensure that unnecessary time and resources are not expended on a project that may prove to be technically difficult. Close interaction with the RA/QA Division is essential to ensure that relevant formulations are produced and funds are not expended on a project which, until animal efficacy is demonstrated, is questionable.**

20. Recommendation: **The original study with iodine should be repeated with a freshly prepared sample of the same formulation, irrespective of its stability on storage. If this produces the same results reported previously, the study will provide a benchmark against which to test all further iodine formulations. If the study in rabbits fails to confirm these results, the project should be abandoned.**

3.8.3 Interaction Between MT Units and Other Divisions

MT units provide a useful service for the Clinical Trials Division, especially with regard to the work on plastic condoms. Information dissemination across divisional lines was regarded as good by MT staff, although the physical separation was, on occasion, a problem. Interactions occurred not only with CT but also to a lesser extent with the Scientific Support Services Division (SSS), CUE, and RA/QA. The new head of RA/QA indicated that she wants to strengthen these links. She intends for RA/QA to do more training of R&D groups in regulatory requirements for good laboratory practice (GLP), informed consent, monitoring, and QA. She wants everyone to respect the SOPs and wants to conduct more in-house audits of procedures. These seem to be excellent objectives that will be of benefit to MT and should be encouraged.

21. Recommendation: **Greater integration of the activities of RA/QA and MT is encouraged.**

3.9 Policy and Research Utilization and Dissemination of Research

3.9.1 Network

The FHI publication Network is of recognized quality, providing information on FHI's research as well as relevant information on the work of other organizations. Typically, an edition of Network will focus on themes such as quality of care, adolescents, family planning, and STDs. FHI has made a considerable effort to determine the types of persons who receive Network, how it is used, and so forth. The translation of the publication into Spanish and French has meant that Network now is available to many Third World audiences with little or no knowledge of English.

The rapid expansion of Network has entailed a substantial, continuing expansion of the budget for the publication. As a result, USAID has recently taken the position that its budgetary support for Network should be decreased and Network should focus principally on disseminating research undertaken by FHI. The evaluation team has considered the perspectives of both FHI and USAID on these issues and concludes that Network should continue its present format and breadth of content, as well as publication in French and Spanish in addition to English. FHI should, however, seek ways to maintain the publication effort at this level with funding from USAID of approximately $750,000 per year (or roughly 6 percent of the annual Cooperative Agreement budget of $12,500,000). It should be FHI's responsibility to demonstrate how it can make up any shortfall between the costs of maintaining the current effort and the recommended level of USAID support. Possible ways of accomplishing this include greater efforts to raise funds from other sources, charging for bulk copies, and seeking ways to reduce the costs of preparing and printing Network issues. (It should be noted that FHI has been successful in obtaining funds from sources other than USAID for some of the costs of Network.) FHI is also advised to (1) obtain information about the use of Network from those who receive copies through bulk mailings and (2) make a limited effort to interview readers (and non-readers) in the course of field visits, including the use of focus group discussions.

22. Recommendation: **FHI should continue its excellent work of producing Network in English, Spanish, and French. It should also continue its practice of not limiting information in Network to research produced by FHI.**

23. Recommendation: **USAID should provide approximately $750,000 (or roughly 6 percent of the annual Cooperative Agreement budget) per year for the publication of Network. It should be FHI's responsibility to secure additional required resources to ensure that Network is continued at its present level of quality.**

24. Recommendation: **FHI should obtain additional information about the use and usefulness of Network which is distributed by bulk copy; it should also hold focus group interviews with readers (and non-readers) during field visits by FHI staff.**

3.9.2 Contraceptive Technology Modules

FHI's new initiative in producing and distributing Contraceptive Technology Updates is designed to expand FHI's reach beyond the Contraceptive Technology Modules Workshops that have been held in various countries but which reach a limited audience. Production of the initial modules has taken more time than is warranted, notwithstanding FHI's desire to have the materials reviewed not only by knowledgeable persons but potential users as well. A staff person has been appointed recently to accelerate the process of review, production, and distribution of the modules. There has been no formal evaluation of the usefulness and impact of the modules, although there is considerable, informal feedback to the effect that the modules are filling a real need regarding current contraceptive information and training.

25. Recommendation: **There should be prompt evaluations of the use, usefulness, and impact of the modules. If there is evidence that the modules are useful and they do not duplicate other available materials, the review and production process should be shortened.**

26. Recommendation: **Work on development of modules not already begun should await the results of the recommended evaluation.**

27. Recommendation: **The survey form included in the update package should be printed on airmail paper with an addressed airmail envelope attached.**

3.9.3 Scientific Articles

The quality of published, original articles in well-known, refereed journals is excellent. More significant recent publications (selected by FHI at the team's request) include practical studies covering the issue of NORPLANT® removals, the optimal number of revisits following IUD insertion, an analysis of oral contraceptive (OC) package inserts, and strategies for family planning service improvement. Under review is an article on the MAQ concept which was first presented at a USAID CAs meeting. FHI staff also authored a consensus statement on breastfeeding as a family planning method and a health policy analysis on breastfeeding and AIDS. Several excellent studies looking at the issue of spermicides and STDs were published, including a recent dosing study of genital irritation after nonoxynol-9 use.

In the contraceptive research and development area, several very useful reviews have been published. They cover international experience with complications and risk factors associated with NORPLANT removal, postpartum tubal sterilization, the current state of research related to pelvic infection and IUD use, and the interaction between TCu-380A acceptors and breastfeeding. Additionally, articles on two recent clinical trials evaluate (1) the progestin-only OC in lactating women and (2) whether pelvic infection after IUD insertion can be reduced by administration of prophylactic antibiotics. Finally, a 1992 paper published in Contraception examines the correlation between condom breakage in use and laboratory test results.

3.9.4 Books and Monographs

Books and monographs are fewer in number. The most recent book, a summary of papers given at a recent meeting in the Dominican Republic on barrier contraceptives, gathers together widely scattered and inaccessible literature on an important issue. It is a winner. Recent monographs include (1) a much-needed but brief first review of the issues surrounding the integration of selected reproductive health services within maternity care services and (2) a thorough report on barrier methods.

28. Recommendation: FHI should consider producing a monograph describing and analyzing more comprehensively current programmatic experiments that are introducing selected reproductive health services into family planning programs in the developing world.

3.9.5 Other Dissemination Activities

In addition to the various types of information dissemination described above, FHI also has organized and/or supported a series of workshops, training courses, and meetings that cover such topics as contraceptive technology updates, research management, clinical trials research methodology, and reproductive health policies and guidelines. Appendix D lists such activities for the period 1985–1994.

3.10 Contraceptive Utilization and Epidemiology

The Contraceptive Use and Epidemiology Division was reorganized in 1993 and combines the former Program Evaluation and Reproductive Epidemiology and STD Divisions. Through its five units, Acceptability and Functionality, Contraceptive Compliance, Contraceptive Benefits and Risks, Contraception and STD/HIV, and Breastfeeding and Postpartum Contraception, CUE pursues its objective of increasing the "availability, acceptance and correct use of a wide variety of family planning methods for the limitation and spacing of births to, and general reproductive health of, women in developing countries."

Working in active collaboration with MT, a large number of condom studies have been performed to evaluate the determinants of breakage and slippage, and acceptability of different condom sizes. While the results of these studies have been carefully reviewed and clearly identify condom age as a factor, a more comprehensive understanding of the determinants of breakage remains to be established. Additionally, the Acceptability Unit has completed a variety of product refinement studies on two promising plastic condom prototypes. Other studies of the plastic condom are in advanced planning stages.

The Compliance Unit continues its work on reviewing and redrafting OC package inserts and studying OC compliance in clinic and non-clinic settings in five countries. The modular questionnaires on compliance have been used by other family planning agencies to monitor quality of services. While the results of the unit's work have been widely disseminated in

publications, expert meetings, and conferences, it is not clear that compliance findings and remaining issues are embedded within the FHI's MAQ initiative.

The quality of the modeling exercises updating mortality risks associated with the use of OCs is high but may not be as urgent as other activities. The Benefits and Risks Unit is participating in a wing of a World Health Organization (WHO)-supported study of prostate cancer and vasectomy and is conducting a pilot feasibility study of its own. Two large U.S. data sets that might offer guidance on this question seem not to have been explored. A study from Jamaica suggests no link between Depo-Provera and cervical cancer. A study from Nigeria finds that women with mild-moderate sickle cell disease are not put at risk by using NORPLANT®.

A variety of high-quality studies on the effectiveness of barrier methods on STD/HIV prevention have been completed by the Contraception and STD/HIV Unit. The unit recently won a National Institutes of Health (NIH) grant to perform a clinical trial on the effectiveness of nonoxynol-9 film in preventing HIV transmission. While the unit did studies on spermicides and HIV prevention with support from The AIDS Technical Support Project (AIDSTECH) earlier, a mechanism to allow support of its policy-relevant work by The AIDS Control and Prevention Project (AIDSCAP), the successor project, has not been identified. A study of the interaction of contraceptive methods, especially Depo-Provera and the OCs, with HIV infection is recognized as being of high priority but has proved elusive because of continuing discussion of difficult design issues.

The Breastfeeding and Postpartum Contraception Unit has completed an array of studies on the lactational amenorrhea method (LAM) and the programmatic issues concerning postpartum contraception. These issues include the use of clinical methods while breastfeeding. The findings have been given to the field through publications and conferences and formally adopted by organizations concerned with this approach to contraception. The work seems reasonably complete and currently of lower priority.

29. Recommendation: **After completing many studies of the latex condom, the understanding of the determinants of condom breakage remain elusive. New protocols should be designed in order to disentangle the roles of condom age, product chemistry, user behaviors, and other factors in condom failure.**

30. Recommendation: **FHI should ensure that compliance studies are well integrated into the MAQ initiative.**

31. Recommendation: **FHI should explore existing data sets that could be useful in exploring the link between prostate cancer and vasectomy.**

32. Recommendation: **The excellent initiatives in the STD/AIDS field should be expanded and should be sensitive to future AIDSCAP policy. AIDSCAP already supports behavioral research; a mechanism needs to be developed to allow AIDSCAP to support epidemiological research on new condoms and spermicides/virucides.**

33. Recommendation: **USAID should support the proposed study of OCs and Depo-Provera and HIV transmission. Once the difficult design issues are worked through, the study should be conducted in a developing country where the protocol can be monitored by qualified persons.**

34. Recommendation: **The LAM clinical trials appear to be sufficient and can now cease. FHI should consider collaboration with FHRCs and experienced in-country investigators on local acceptability studies of Lea's Shield, Femcap, and the female condom. Research on specific issues, such as the acceptability and feasibility of reuse of the female condom, which are considered critical to the overall assessment of this method, should be continued by FHI.**

3.11 Service Delivery Research

Research aimed at the improvement of family planning service delivery has led the Service Delivery Research Division into an important series of studies examining the quality of care, resource allocation and sustainability, and programmatic outcomes of the introduction of new contraceptive methods and delivery systems, and, in 1994 and still mostly under development, issues relating to the integration of STD/HIV prevention into family planning programs. The work of SDR is closely integrated with the MAQ initiative.

Research looking at the costs of family planning services and programmatic sustainability is an area of special excellence. With support from the United Nations Population Fund (UNFPA), the SDR staff has produced a useful manual containing a methodology by which program managers can evaluate family planning costs. It would be useful at the current time for SDR to explore how this methodology can be linked to systems of financial accounting that several family planning associations in Latin America have developed as part of an effort to achieve increased financial sustainability. SDR is also now positioned to research the more complex issue of costs as other reproductive health services find their way into the programmatic mix.

SDR has examined carefully the rationale of selected medical practices that may impede the success of programs without contributing to acceptor safety. For example, it is now clear that follow-up visits after IUD insertion can be reduced substantially without compromising safety. Wider adoption of this finding will produce important savings in the delivery of family planning services.

SDR has had good success in attracting USAID Mission buy-ins for its work. In FY 1994, buy-ins and private funding were 40 percent of its budget.

In collaboration with other CAs and other FHI divisions, SDR has developed guidelines on introducing (and reintroducing) family planning methods and participated in meetings and seminars to promote the findings of its work. The past and present lessons concerning Depo-Provera introduction have yet to be summarized in a practical manual that can be given to program managers.

35. Recommendation: **SDR should explore how its conceptual work in the area of cost studies can be linked with systems of financial accounting that several Latin American family planning associations have developed as part of an effort to achieve greater financial sustainability.**

36. Recommendation: **SDR should give priority to studying the complex task of estimating the costs of integrating other reproductive health services (STDs, Pap smears, etc.) with family planning.**

37. Recommendation: **Without unnecessary replication of studies, the issues surrounding introduction/re-introduction of Depo-Provera and NORPLANT® should be addressed in important countries with a view to developing a manual based on lessons learned in the field.**

38. Recommendation: **Planning should begin for the introduction of the plastic condom into family planning programs and through other outlets.**

3.12 Field Operations

The Field Operations Division (FO) is essentially a support or facilitating division. Its objectives include identifying country/regional needs, providing information on FHI's activities to USAID Missions, and serving as liaison to FHI's country and regional offices. FO staff works to ensure prompt responses to requests for technical and other assistance from, and requests for proposals (RFPs) issued by, Missions and attempts to identify new opportunities and resources to match FHI's abilities to countries' reproductive health needs. FO, and its predecessor entity the Field Development and Training Division, has played a substantial role in developing the FHRCs, including assisting them to become more financially independent. Additionally, FO staff has collaborated with PRU and SDR, along with other CAs, to introduce new contraceptive methods (NORPLANT®) or reintroduce existing ones (Depo-Provera) in several countries.

39. Recommendation: **The team supports the idea of modest expansion of FHI representation in countries that present substantial learning opportunities for service delivery or other research.**

40. Recommendation: **The team favors a more proactive approach by FHI to make USAID Missions aware of FHI's research capability and potential for strengthening programs. FO should develop such a strategy with other FHI divisions and plan appropriate visits by scientific staff to Missions in countries presenting special opportunities.**

41. Recommendation: **In order to better understand the process of "graduating" FHRC institutions and to provide guidance for the process for other institutions in the future, FHI should assess the research and financial status of several of the "graduated" FHRCs. SDR should be involved in this research.**

4. PERSONNEL AND MANAGEMENT ISSUES

4.1 Management Structure

The management structure of FHI encompasses three major scientific components: Research and Development Department, Reproductive Health Programs Department (referred to in this evaluation report as Population Program Department), and the AIDS Control and Prevention Department. In addition, there are also corporate directors for Medical Affairs, International Medical Affairs, and Scientific Affairs. There are also management and administrative components. Vice presidents or directors have responsibility for the staff in each major component. The Research and Development and Population Program Departments are divided into divisions with a director for each division. Interaction among divisions or major components is accomplished by a variety of mechanisms discussed above. Strong leadership for the whole of FHI is provided by the president. The vice presidents for the Research and Development and the Population Program Departments have organized their divisions well and have appointed excellent people to be division directors. The recent move of Dr. Dorflinger to Clinical Trials and the recruitment of Dr. Campen, an acknowledged expert, to RA/QA is viewed as highly positive. The recruitment of Dr. Cates as Corporate Medical Director and Director of Epidemiology is also very positive, as was stressed by representatives of other CAs. Thus, there seems no need to change the management structure as currently constituted.

4.2 Staffing

FHI has been very successful in recruiting and retaining qualified staff. The evaluation team found that most staff members are highly motivated and take pride in working at FHI. Staff also feel that higher levels of management are open and receptive to proposals for project work that fall within the guidelines of the Cooperative Agreement. Furthermore, even though there are formal lines of management, junior staff members felt that they had access to senior staff, when needed, without necessarily going through their immediate supervisors. This flexible open door approach is to be commended, since, in an organization as large and complex as FHI, bureaucratic paralysis can easily occur.

In the Population Program Department there are several areas where additional staff members are required but management is already seeking candidates for these positions. There do not appear to be areas where a reduction in staff is needed. There are several instances where staff members work in both Women's Studies and under the Cooperative Agreement. The evaluation team is supportive of this arrangement inasmuch as it facilitates coordination and linkage of related activities.

Regarding the contraceptive research and development area, FHI seems to have had no trouble in recruiting well-qualified personnel at all levels, the recent addition of senior staff being a prime example. Certain staffing needs in MT have been noted. Also, there has been a new addition in Biostatistics which will broaden the expertise of this division in sampling techniques. Additional labor may be needed here depending on which Phase III clinical trials are actually initiated.

4.3 Training

FHI has a policy of training and personnel development which is to be commended. However, increased effort could be useful in the area of computer and management training. Several staff members, especially at junior levels, indicated that they would welcome greater opportunities for personal development and training which would assist them in performing their jobs better.

42. Recommendation: **More advanced training courses for selected computer software programs should be provided. Needs could be determined by a survey of personnel.**

43. Recommendation: **Training in management skills and techniques should be provided for supervisors, particularly at lower levels.**

4.4 Computer Services

FHI has already begun to upgrade the computer services and networking. However, further improvements are necessary, and this is a high priority item. The conversion of documents and other materials from personal computer to Vax is time consuming, and the Vax is sometimes slow for access and downtime creates problems. The Vax system can be maintained for central administrative functions and hardware intensive data analyses. Greater server capacity seems essential. The ability to access Internet through only one central node needs to be remedied. It was understood that this was to ensure security of FHI's computer system and the problem would be fixed by September 1994.

44. Recommendation: **All personnel needing to send and receive e-mail via Internet should be able to do so.**

45. Recommendation: **The switch from dumb terminals accessing the Vax to personal computer networks should be accelerated. Greater server capacity is badly needed.**

4.5 Internal Communications and Information Dissemination

FHI has a very effective system of internal communications and information dissemination. Illustratively, Appendix F lists FHI internal meetings for March 1994.

46. Recommendation: **Without in any way impeding the current excellent system for internal communication, FHI might review the schedule and purposes of various meetings to determine whether some consolidation or streamlining is in order.**

4.6 Reporting Requirements

Appendix G lists reports required under the Cooperative Agreement. Based on a review of FHI's semiannual reports, the team concludes that the reports are comprehensive, well written, informative, and, particularly since activities have been reported on by region, well organized. While only a few FHI staff members stated that reporting requirements were onerous, the question was raised as to whether USAID would be satisfied with annual reports. In the course of discussions about reporting requirements at FHI with the participation of the USAID technical monitor, there was an indication that annual reports might suffice. There was also a suggestion that annual reporting might be linked to preparation of the annual work plan, which would further reduce the report preparation load. Finally, there was a consensus that the proposed reduction in frequency of reporting to USAID could be compensated for by increased participation by the USAID technical monitor in FHI's Scientific Committee meetings and TAC meetings.

Mention was also made of a new Executive Information System (EIS) that is being developed at FHI which will reduce the amount of time and work required to produce financial reports on program activities. This will be useful not only for senior management but also for Field Operations and responding to *ad hoc* requests for information from USAID and other organizations in the population field.

47. Recommendation: **USAID should consider requiring annual, rather than semiannual, reports from FHI. Further, in the interests of reducing the reporting workload, FHI should explore how annual reporting could be combined with preparation of annual work plans.**

5. BUDGETING AND FUNDING

5.1 Allocation of Funds

As noted in Section 1.2, the allocation of Cooperative Agreement funds within FHI is made in the course of Scientific Committee and other meetings in which USAID staff participates. The budget planning process begins in January when, in a two-day meeting attended by all division directors and USAID, a broad look is taken at current and future program needs and priorities. This gives FHI staff a sense of strategy for the year. Following this meeting, a preliminary rough budget, including a "wish list," is prepared by each division and submitted to USAID by late March/early April. A meeting of senior FHI management and USAID representatives is then held where USAID essentially ranks the program/budget items. Key technical program issues are further discussed during the TAC meeting in early summer. The summer meeting of the Scientific Committee takes account of TAC inputs, and this, together with other changes that have occurred since spring, and, based on actual availability of funds for the coming year, results in a more detailed, revised budget document that is submitted to USAID. At the fall meeting of the Scientific Committee attended by USAID, each division presents its proposed work plan. With the approval of the Scientific Committee and USAID, the nine-month planning process is completed and FHI is ready to implement the work plan beginning the first of October. Generally, two-thirds of the work plan budget is for ongoing activities.

It is the team's judgement, based on an assessment of the Cooperative Agreement, the work plans, and Appendix H, a (summary sheet showing expenditures by division and by year), that funding allocations do relate to the objectives of the Agreement. There have been some trends in expenditures and budgets among divisions as Appendix H shows. Contraceptive research and development accounted for 56.3 percent of total central expenditures in FY 1992 and 47.5 percent in FY 1994. Population program research and related activities went from 41.3 percent in 1992 to 49.8 percent in 1994. Within contraceptive R&D, MT's budget increased from $1,205,438 in 1992 to $2,930,348 in 1994, while RA went from $301,474 in 1992 to $672,703 in 1994. These increases are appropriate. MT had substantially increased demand from CLM for testing condoms and prospectively oral contraceptives which has meant, *inter alia*, budget increases for staff, travel, and so forth. RA/QA, which grew out of the Statistics Division, now stands alone and, with its workload increasing, may grow even larger in the future. Regarding the Population Program Research area, the greatest proportional increases have been in PRU and SDR. The PRU increase reflects FHI's greater emphasis on disseminating the results of FHI's research. The budget for SDR increased in response to USAID interest in conducting programmatic research in the areas of contraceptive introduction and Maximizing Access and Quality of Care. Thus, this new division expanded its activities significantly beyond that of the original core activities of the Economic Unit. The budget for 1994 is predicted to continue to grow as projects developed in 1994 are implemented and as new projects in the area of integrating reproductive health services into family planning programs are developed and implemented.

Appendix I portrays budget trends in terms of regions. The Africa region budget increased from $1,672,000 in FY 1992 to $2,278,000 in FY 1994, while Latin America and the Caribbean grew from $1,259,000 to $1,604,000. Asia and the Near East had experienced a decline from $2,234,000 to $1,255,000, accounted for in part by a decrease in the amount of buy-ins. There

were major increases in Europe/USA and Interregional ($1,953,000 to $3,068,000 and $4,964,000 to $7,641,000, respectively). The increase for Europe/USA is attributable to the shift away from clinical research in some developing country settings to ensure compliance with USFDA standards. This translates into higher costs as well as need for more data. The increase in the Interregional category is a result of (1) increased information dissemination (which usually is not budgeted on a country-specific basis); (2) costs associated with condom production surveillance, including new equipment, additional staff, facilities, and travel; and (3) a substantial amount of training which was not organized on a country-specific basis. From another perspective, FHI's research agenda also influences budgetary allocations among regions. Latin America, for example, has substantial research capability which helps account for the increase in the budget for that region. While there is generally less research capability in Africa, there has been an increase in the budget because of the increased interest in STDs/HIV.

Staff of the Research Division of USAID/Washington has stated that from USAID's perspective, FHI's most important area of work under the Cooperative Agreement is contraceptive research and development, especially Phase II and III clinical trials. USAID staff would like to see slightly more than half of the total budget of the Cooperative Agreement devoted to contraceptive research and development. In developing plans for the next Cooperative Agreement, FHI should take this fact into account.

5.2 Buy-ins

Appendix H also shows the amount for buy-ins or add-ons for each division. As would be expected, Field Operations received by far the largest amount, i.e., 78 percent with Service Delivery Research a somewhat distant second. Buy-ins represent 19 percent of total funds. The evaluation team has the impression, based on both FHI documents and meetings with FHI staff, that buy-ins have generally supported FHI's program objectives and have not been an inappropriate use of staff or other resources. The team was informed that FHI's work in Nepal, which has thus far been supported by a buy-in, may depend on central funds in the future. Given the character of the work in Nepal in the context of FHI's program objectives, this may not represent the optimum allocation of FHI funds.

5.3 Budget Increases and Decreases

Appendix H shows that there have been no overall budget reductions over the life of the current Agreement. Rather, overall, there has been a substantial increase. When additional funds have become available, FHI appears to have used them effectively. This seems to be accounted for by the availability of the "wish list," the willingness of USAID to turn to FHI to carry out additional activities that are a priority for USAID, and the responsiveness of FHI to requests from its principal source of support.

Early in FY 1994, USAID informed FHI that there might be a substantial budget reduction for FY 1995. Although this ultimately did not occur, FHI prudently took certain initiatives in 1994 to reduce spending, including reducing the travel budget. This obviously affected attendance at scientific meetings, reduced opportunities for promoting the image of FHI's corporate excellence, and had implications in terms of individual personnel development and acquisition of expertise.

48. Recommendation: **Although, in times of budgetary constraints, reduction of travel budgets is an immediate way to solve the cash shortage, FHI is urged to restore these cuts as soon as possible.**

5.4 Use of USAID Funds as Seed Money

FHI has used USAID funds as seed money in several instances. These include expanding work in the area of epidemiology, support for staff salaries for development of proposals to be submitted to NIH, and initiating FHI's work in benefits and risks. FHI is currently initiating work with USAID funds on a study of the relationship between Depo-Provera and bone growth in adolescents. The process entails simply securing USAID's concurrence. In cases where FHI cannot use USAID money as seed money, for example in Vietnam, FHI uses its corporate funds.

6. RELATIONSHIPS WITH OTHER ORGANIZATIONS

In the briefing materials prepared for this evaluation, each division of FHI identified institutions with which it has been collaborating and described the activity briefly. Collaborating institutions include CAs, donor foundations, U.S. government agencies, international organizations, international NGOs, universities, and developing country institutions. Clinical Trials, for example, is working with three CAs as well as Johns Hopkins University Medical School, NIH, and WHO. MT has relationships with the Program for Applied Technology in Health (PATH), John Snow Inc. (JSI), the International Planned Parenthood Federation (IPPF), UNFPA, the Center for Disease Control and Prevention (CDC), WHO's Global Programme on AIDS, and, naturally, USFDA. PRU is collaborating with 12 CAs plus CDC, WHO, UNFPA, the Pan American Health Organization (PAHO), and the International Women's Health Coalition (IWHC). In its work with CAs, PRU has had six activities with the Association for Voluntary Surgical Contraception (AVSC), five with Pathfinder, 10 with IPPF and its affiliates, and six with Johns Hopkins Program for International Education in Reproductive Health (JHPIEGO). CUE has had collaborative activities with eight CAs and five activities with WHO. SDR is collaborating with 10 CAs and UNFPA and PAHO. (As is discussed in Section 7.5 below, all USAID Missions responding to the request for an evaluation of FHI stated that FHI collaborated very effectively with other CAs.)

The evaluation team had discussions, mostly by telephone, with representatives of CONRAD, PATH, The Population Council, AVSC, USFDA, WHO, the National Institute of Child Health and Development (NICHD), and IPPF/Western Hemisphere Region (WHR) about their interactions with and perceptions of FHI. The persons interviewed felt that FHI provided a very useful resource in the area of research, especially clinical research and large clinical trials, and sought closer collaboration.

PATH staff members indicated that greater cooperation between FHI and PATH on a condom testing project (which was funded by FHI as a pass through to PATH) could have provided opportunities for additional information and further analysis which would have improved the process of product development. PATH staff members noted that cooperation between the two organizations has improved recently and an FHI-organized meeting to be held in the near future will discuss several condom-related issues. USAID is also funding PATH via FHI for design and development of a single-use injection device for delivery of Depo-Provera and possible other substances.

AVSC staff members noted that it is their policy to identify organizations that can conduct research on service delivery issues rather than developing such research capability themselves. They see FHI as an important resource for research, and, therefore, good collaboration is essential. There have been some problems in achieving a good working relationship in several instances, including Kenya and Mexico. The problem stems in part from FHI's research focus as contrasted with AVSC's service orientation, in part from FHI's stance of "independence," and in part from earlier disagreements about the utility of quinacrine as an agent for nonsurgical sterilization. In other instances, for example a postpartum IUD project in Africa and an incipient acceptability research project in Jordan, collaboration between FHI and AVSC is good.

The Population Council has collaborated with FHI in NORPLANT® introduction, and the two organizations are working together on introduction of Depo-Provera. A member of the Council's senior staff usually attends FHI's TAC meetings, and there is cooperation on Maximizing Access and Quality. USAID staff responsible for monitoring the Population Council's INOPAL project commented on the effective way that FHI and the Council collaborate in the operations research area in Latin America. The Council would like to have greater collaboration with FHI in R&D but recognizes that the failure to accomplish this rests with both organizations.

Given that CONRAD did not have its own in-house data analysis capability, it was mandated by USAID to use FHI for such services. This has not always worked well in the past, partly because of the overload of FHI's Biostatistics Division and partly because the priorities of FHI and CONRAD were not always the same. Communication has been reasonable but could be improved. CONRAD would like more collaboration in the area of barrier methods and spermicide/anti-microbial/antiviral compounds and feels that greater integration within FHI of the RA/QA, Clinical Trials, and Biostatistics Divisions would be helpful.

FHI is conducting studies on the polyurethane condom under contract to NICHD. NICHD indicated that these studies were progressing well. FHI has been represented at meetings on female condoms, quinacrine, vaginal irritation, and nonoxynol-9 and contributed significantly. USFDA also had very positive views regarding interaction with FHI. USFDA feels that the revised labeling for OCs has proved extremely helpful and is eagerly waiting for revised labeling for progestin minipills. Such simplified, revised labeling may prove helpful in making minipills available over-the-counter.

FHI has attempted to establish formal links with WHO, but this has not occurred because of legal concerns on the part of WHO. Nevertheless, informal links are good.

SDR collaborated with IPPF/WHR and several of its affiliates in Latin America in the area of costing of family planning services.

The evaluation team did not find evidence of duplication of work among CAs. There clearly are opportunities for better collaboration, however, and there seems to be progress in this direction.

49. Recommendation: **FHI should take more initiative in seeking collaboration with CAs which have complementary roles and skills, especially The Population Council, CONRAD, and AVSC. USAID should encourage other CAs to collaborate with FHI.**

7. FHI RELATIONSHIPS WITH USAID

7.1 Implications of "Substantial Involvement"

The Cooperative Agreement specifies that USAID, through the Cognizant Technical Officer (CTO), will be "substantially involved during the performance of the Cooperative Agreement." The Agreement then spells out the many ways this is to be accomplished, including the following:

- "collaborative involvement in the development and approval of an annual work plan..."
- "collaborative involvement in selecting and approving TAC members, consultants, and expert committee members; establishing priorities and developing and modifying the scientific research agenda..."
- "approval of each stage of activities carried out under this agreement including strategic plans, protocols..."
- "consultation and approval for all activities identified by USAID missions for possible inclusion in this agreement."

Given the very substantial involvement described above, the issue of the relationship between USAID and FHI takes on special importance. If the relationship were not good, it is difficult to see how the Cooperative Agreement could be implemented in a productive manner. Fortunately, the evaluation team found that, overall, relationships are excellent and are so perceived by key staff of both organizations.

7.2 Strengths and Weaknesses of the Relationship

Strengths of the relationship include the following: USAID has in FHI an excellent resource to pursue the former's priority research and development agenda; FHI is adept at responding to needs of both USAID/Washington and USAID Missions; the current Technical Monitor is very competent; FHI is useful not only to the Research Division of USAID's Population Office but also to CLM, and probably to a lesser degree to Policy and Evaluation and Family Planning Service Delivery (FPSD).

There appear to be few weaknesses in the relationship between USAID and FHI. They include, importantly, FHI's reliance on one organization for a very substantial portion of its total budget; *ad hoc* requests from USAID which, at times, delay achievement of FHI's planned activities; CLM's view in the past that FHI was not as responsive to its needs as it was to the needs of USAID's Population Office Research Division; and the substantial turnover in USAID technical monitors during the period of the Cooperative Agreement.

7.3 FHI's Assessment of USAID

In the words of senior staff of FHI, "USAID is incredibly cooperative." FHI recognizes that the Cooperative Agreement is with the Research Division of USAID's Population Office, which means that USAID has a greater interest in FHI's research work than its work concerned with service delivery or education and training. FHI must also balance its response to the needs of USAID/Washington with its responses to USAID Missions. It is FHI's perception that currently the Missions are pressing their agendas more forcefully than is Washington.

7.4 USAID/Washington's Assessment of FHI

USAID staff find FHI "very responsive to USAID/Washington and to the USAID Missions." As noted above, in the past, CLM found FHI less responsive. This apparently has changed. Staff of the FPSD and Policy Divisions of the Population Office were generally positive about FHI, although the former commented on the need for a greater field presence. This undoubtedly reflects, in part, the views of several of the Missions.

7.5 USAID Missions' Assessment of FHI

Fourteen Missions responded to USAID/Washington's request for an evaluation of FHI's performance. Issues to be addressed included success in identifying and implementing research activities; coordination with host-country institutions and CAs; strengthening management and research skills of developing country investigators and institutions; project management, including responsiveness to Missions, appropriate skills, and timely reporting; suggestions for changes and improvements; and recommendations for the future.

Generally speaking, Missions were very positive about FHI's performance. With respect to identifying and implementing research activities, only the Missions in Kenya and Senegal raised questions as to whether FHI put more emphasis on its research interests as opposed to responding to local research priorities. Regarding coordination with host-country institutions and other CAs, there was unanimity that FHI excelled in this area. Only one Mission, Senegal, reported that FHI was weak in strengthening management and research skills of developing country researchers. All other Missions indicated that FHI helped either in the research or management area, or both, or that locals (the Philippines) already had the needed skills.

All Missions confirmed that FHI was responsive to Mission needs. The Senegal Mission noted that FHI did not always alert the Mission to impending problems and that there was too much FHI staff turnover. The Malawi Mission commented that FHI managed one project very well but that there were delays in the second (female condom) study. All Missions felt that FHI staff had the appropriate skills. Regarding timeliness of reporting, eight Missions stated that FHI had done a good job. The Mission in India said that reporting in the final year of the project was delayed or incomplete and that some reports were not submitted at all. The Senegal Mission noted that, while English versions of reports were on time, there were delays in receiving the French versions.

There were relatively few suggestions from the Missions for improvements, increased emphases, or future directions of the Cooperative Agreement. Although the Mission in Chad reported no FHI activities currently, it did suggest focusing on integrated care and cost

recovery and recommended a stronger field presence. The Honduras Mission identified "adolescents, men and gender," quality of care, and cost recovery as areas warranting greater attention. The Niger and Bolivia Missions emphasized operations research (OR), while Ghana wanted more attention to medical barriers. Bolivia emphasized family planning and sex education for adolescents and men and increased attention to STDs/HIV in reproductive health services. The Malawi Mission would like FHI's mandate broadened to include STDs/HIV and maternal mortality and morbidity and would like further studies of the female condom. The Philippines Mission recommended increased FHI activity in introduction of new contraceptives such as NORPLANT®.

The Senegal Mission raised an interesting issue which warrants mentioning in this report. In its buy-in, the Mission, in an effort to reduce its management role, tried to link several activities related to NORPLANT®. This included clinical trials, diffusion of results, and expansion of NORPLANT® to model clinics for operations research which would, in turn, serve as a basis for introducing NORPLANT® nationwide. FHI was chosen to take the lead in this effort. However, while FHI has good research capability, the Mission considers that FHI's expertise in management and programmatic issues is not as developed. The Mission recommends, therefore, that "if contraceptive research is to be continued overseas that the implementing organization must also have the managerial and programmatic ([example:] supervision systems) expertise to provide technical direction to effectively introduce a technology into use." The issue of the scope of FHI's role is discussed further in Section 8.2 which follows.

8. FUTURE DIRECTIONS OF A FOLLOW-ON PROJECT

8.1 Contraceptive Research and Development

FHI has done good work in the past and should continue to emphasize its strengths in materials technology and clinical trials. Conducting clinical trials to the highest standards is likely to prove cost effective in the long run. The deficiencies in the Filshie clip studies at some overseas sites are an example of the problems that can arise if USFDA approval is needed so that USAID can distribute a new contraceptive method. If USAID is not interested in distribution of a method, then FHI should not be using Cooperative Agreement funds for studies on such a method, unless specifically requested by USAID to do so. There seems no need at this time to restrict or narrow the focus of FHI's R&D activities. Indeed, it is the feeling of the evaluation team that these should be expanded and FHI should make greater efforts to initiate new activities in collaboration with other CAs, which could compensate for the loss of proposed Phase III trials with the Lea's shield and further development work with NET pellets and microspheres. It could be argued that FHI could be more "hard nosed" when assessing ongoing projects and drop at an earlier stage those not showing promise. Several projects have dragged on for years and, if definitive experiments and decision points had been identified, these might have been terminated earlier or given higher priority to reach the decision point. There is the impression that some of these projects were maintained limping along because the portfolio of other opportunities was slim. This brings the argument back to the need for FHI to be more proactive to develop new initiatives, such as the successful interaction of MT with CLM, either alone or in collaboration with other CAs, which will provide alternative choices for action.

50. Recommendation: **Priority for clinical studies should be placed on products that will be distributed by USAID. Where appropriate, clinical trials should be performed to USFDA standards.**

51. Recommendation: **There should be a greater willingness to drop unpromising lines of investigation at an earlier stage.**

52. Recommendation: **The focus of FHI's R&D effort should be expanded, especially in collaborative efforts with other Cas.**

53. Recommendation: **The Quality Assurance/Production Surveillance component should be kept within the next Cooperative Agreement.**

54. Recommendation: **In developing plans for the next Cooperative Agreement, FHI should take account of USAID's view that contraceptive R&D, especially Phase II and III clinical trials, is FHI's most important area of work, and the proposed budgetary allocation should reflect this fact.**

8.2 Population Program Department

The current Cooperative Agreement project paper gives primary emphasis to the development, introduction, and evaluation of new and improved contraceptives for family planning. In point of fact, FHI is already moving to embrace the broader paradigm of reproductive health, for example, through research on the relationship between STDs/HIV and contraception for family planning. The evaluation team believes that this trend should be continued in the next project in recognition of the fact that developing country programs increasingly have reproductive health as their overall focus. The team also finds that the range of activities in FHI's Population Program Department forms a logical and coherent whole, encompassing (1) development and implementation of strategies for introducing new contraceptive methods; (2) studies to improve acceptability of and compliance with contraceptive use; (3) research and interventions to improve access to contraception; (4) research to support family planning service delivery programs; and (5) continued studies to evaluate both long- and short-term benefits and risks of contraceptive use. The team believes that FHI should continue these activities in the next Cooperative Agreement.

The Scope of Work raised the issue of whether FHI is trying to do too much, and if so, what activities should be de-emphasized. This issue is not unrelated to the issue raised by the Senegal Mission, discussed in Section 7.5 of this report. The Senegal Mission noted its desire to be able to turn to a single CA to carry out a full range of activities from research on contraceptives to operations research to helping to extend new contraceptives to programs of national scope, which implies management, supervisory, and training skills. The evaluation team concludes that FHI should retain its focus on research—which is its great strength—and, of course, be active in education and training and dissemination activities which are closely linked to that research. FHI should not, however, in this or the proposed next Cooperative Agreement, attempt to become a "general purpose" CA but rather continue to link up with other CAs which have complementary skills and expertise, even though the coordination and collaboration which this implies sometimes presents problems. In summary, FHI's expansion or broadening of the scope of its work should be from family planning to reproductive health rather than from research to "general purpose."

The team finds that the current organization, procedures, and staffing of FHI are, in general, appropriate for the next Cooperative Agreement and should not be altered in any major way. Additional staff and some organizational adjustments will be needed to implement the paradigm shift from family planning to reproductive health. Also, there should be increased efforts to establish coordinating mechanisms to ensure that activities under the next Cooperative Agreement are coordinated with activities carried out through AIDSCAP and Women's Studies.

55. Recommendation: FHI should continue its trend toward embracing the paradigm of reproductive health.

56. Recommendation: **FHI should retain its focus on research and be active in education, training, and dissemination of information which are linked to that research. FHI should not attempt, in the current or proposed next Cooperative Agreement, to become a "general purpose" CA but rather should continue to collaborate with other CAs which have complementary knowledge and capabilities.**

57. Recommendation: **The Women's Studies Project should be involved not only in the MAQ Working Group but in other relevant Working Groups, including, e.g., the Group concerned with postpartum contraception. The Women's Studies Project should also participate in planning any research looking at the effects and costs of integration of elements of reproductive health services into family planning.**

58. Recommendation: **AIDSCAP should be represented on FHI's Family Planning/Contraception/STD-HIV Working Group and Adolescent Reproductive Health Working Group.**

59. Recommendation: **FHI staff supported under the Cooperative Agreement, AIDSCAP staff, and AIDSCAP subcontractors should hold several informal (and small) meetings in the next fiscal year to define the critical research areas that are likely to influence AIDS control policy in the next years. Funds should be available under the next Agreement for FHI to pursue the most promising studies.**

8.3 Monitoring the Next Cooperative Agreement

Finally, there is the issue of how to monitor effectively the next Cooperative Agreement, an important issue given USAID's role of "substantial involvement". Because the Agreement is funded by the Research Division of USAID's Population Office, and because that Office sees FHI's most important activity as contraceptive R&D, there are undoubtedly activities funded under the Agreement that are less closely monitored and perhaps less appreciated. One result is that FHI and USAID may not be realizing the full synergistic potential of FHI's work, which, as noted earlier, appears to the evaluation team as logical and coherent. The team concludes that it would be useful for USAID to develop a monitoring structure for the next Agreement which (1) gives adequate attention to all areas of activity funded under the Agreement and (2) recognizes and stimulates the synergistic potential of the totality of FHI's work supported by the Agreement.

60. Recommendation: **USAID should develop a monitoring system for the next Cooperative Agreement which gives coordinated attention to all areas of activity funded by the Agreement.**